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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/613,961 | 07/11/2000 | A. Bart Flick | 06772-0110 | 1541 |

23370 7590 06/13/2003

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
SUITE 2800
ATLANTA, GA 30309

| EXAMINER | |
|---|---|
| LEWIS, KIM M | |
| ART UNIT | PAPER NUMBER |
| 3761 | |

DATE MAILED: 06/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/613,961 | FLICK, A. BART | |
| | Examiner | Art Unit | |
| | Kim M. Lewis | 3761 | |

*-- Th MAILING DATE of this communication app ars on the cov r sheet with the correspond nce address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4)☒ Claim(s) *1 and 3-22* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☒ Claim(s) *15-18* is/are allowed.

6)☒ Claim(s) *1,3-14 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed on 4/1/03 has been received and made of record in the application file wrapper. Claims 1 and 3-22 are pending.

### *Allowable Subject Matter*

2. The indicated allowability of claims 1-14 and 19 is withdrawn in view of the newly discovered reference(s) to U.S. Patent Nos. 6,004,667, 5,520,664 and 4,615,705. Rejections based on the newly cited reference(s) follow.

3. Claims 15-18 are allowed.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,520,664 ("Bricault, Jr. et al.").

As regards claims 1 and 4, Bricault, Jr. et al. disclose polymeric implants (col. 4, lines 64 and 65) having antimicrobial coatings, such as, gold, silver, platinum, *etc.* As regards applicant's recitation of no galvanic cell action, note col. 5, lines 48-64.

The applicant should note that silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

Bricault, Jr. et al. fail to explicitly teach that the resistance of the metals is less than 1000 ohms/cm. However, since the applicant discloses some of the same conductive materials as those disclosed by Bricault, Jr. et al., (*e.g.*, silver and gold), it is inherent that the same metals have the same resistance. Note applicant's admitted disclosed resistances on page 32-33 of the specification.

As regards claims 13 and 14, Bricault, Jr. et al. disclose a tubular shaped catheter (Figs. 5 and 6a), which is capable of draining a wound or body cavity (thereby being a wound drain).

6. Claims 1, 4 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,004,667 ("Sakurada et al.").

As regards claims 1 and 4, Sakurada et al., disclose a bandage or wound dressing comprising a fibrous substrate coated with silver or nickel, which inherently has a resistance of 1000 ohm/cm or less, according to applicant's own admission (see the specification).

Sakurada et al. also disclose that **the metallic ions may be distributed into the body without galvanic cell action** (col. 5, line 43-48, col. 6, lines 32-39 and col. 12, line 21- col. 13, line 22)

As regards altering the electrodynamic process of a portion of the body, silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

As regards claim 19, Sakurada et al. disclose a medical device (bandage) for treating a portion of the body, comprising at least one layer of a conductive material (201) coated with silver or nickel, having an inherent resistance of less than 1000 ohms/cm (see the specification).

Sakurada et al. further disclose that the conductive layer inherently comprises a biologically inert polymer since it is used on the human body, wherein no galvanic cell action or external energy source is required to alter an electrodynamic process or electric parameters of the portion of the body.

The applicant should note that steps (b) and (c) inherently occur when the metallic ions from the substrate enter the body.

7. Claim6 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,615,705 ("Scales et al.").

As regards claim 6, Scales et al. disclose antimicrobial implants (*e.g.*, orthopaedic plates, pins and artificial joints) comprising at least one layer of conductive

material (metallic silver). Applicant admits in the specification that silver has a resistance of less than 1000 ohm/cm. Scales et al. further disclose that the layer of conducted material is coated on an implant constructed from a bioinert material (*e.g.*, a non-toxic synthetic plastics material (polymer).

Additionally, the applicant should note that it is inherent in the disclosure that no external energy or galvanic cell action is required to alter an electrodynamic process of a portion of the body since the application of silver ions to the body inherently performs the function of altering the electrodynamic process of a portion of the body to which it is applied . The examiner concedes that at col. 3, lines 68-col. 4, line 3, Scales et al. mentions that in order to promote galvanic action producing silver ions, specific silver alloys may be used. However, the applicant is directed to col. 4, lines 49-52, wherein it is disclosed that silver ions are produced using metallic silver and col. 5, lines 24-31, wherein it is disclosed that silver ions are produced using bioerosion.

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scales et al.

As regards claim 7, Scales et al. fail to teach the medical appliance a dental appliance. However, the examiner contends that the technology used to the apply metal coatings to the pins and plates of the disclosed endoprosthetic implants of Scales et al., can also be used to coat dental appliances.

Furthermore, the examiner contends that dental implants are a form of an endoprosthetic implant. And, one having ordinary skill in the art would have been motivated to place an antimicrobial coating on any implant, including a dental implant (appliance) for the purpose of preventing antimicrobial growth thereon.

11. Claims 3, 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.s. Patent No. 6,004,667 ("Sakurada et al.").

As regards claim 3, Sakurada et al. fail to teach the substrate is constructed from polyester and acrylic fibers or a gauze. However, since gauze is conventionally constructed material, such as, for example, cotton, one having ordinary skill in the art would have found it obvious to select cotton gauze because it is breathable.

Additionally, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

As regards clams 5 and 8-12, Sakurada et al. fail to teach the bandage is shaped for use around external fixture pin structures, shaped for use around ostomy sites, shaped for use around tracheostomy sites, shaped for use around catheter sites, and shaped for packing body cavities. However, it has been held that the shape of a prior art device is a design consideration within the level of ordinary skill in the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). As such, one having ordinary skill in the art would have found it obvious to change the shape of the bandage to fit the portion of the body for which the device is intended.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

**Kim M. Lewis**
**Primary Examiner**
**Art Unit 3761**

kml
June 10, 2003